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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
NIEBAUER, RONALD T	
ART UNIT	PAPER NUMBER
1654	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/572,239	VAN NORREN ET AL.	
	Examiner	Art Unit	
	RONALD T. NIEBAUER	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 July 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19-36* is/are pending in the application.

4a) Of the above claim(s) *20-22,26,27 and 30-36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19,23-25,28-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/21/09 has been entered.

Applicants amendments and arguments filed 7/21/09 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed is herein withdrawn. Briefly, the claim amendments have overcome the previous 112 2nd, and 112 1st rejections.

Applicant's previously elected (2/22/08) with traverse Group II (claims 19-29) and the following species:

Guanosine equivalent (GTP increasing component) – GUANOSINE

Carbohydrate – GLUCOSE

(no other species were identified for the composition).

As discussed below, the elected species were found in the prior art. Any art that was uncovered during the search for the elected species that reads on non-elected species is also cited herein. In accord with section 803.02 of the MPEP the claims to the elected species are rejected and claims to nonelected species held withdrawn.

Claims 1-18 have been cancelled.

Claims 30-36 are to a non-elected group. Since applicants elected guanosine and glucose as the species, claims 20-22,26-27 which include additional components are to nonelected species.

Claims 30-36 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 2/22/08.

Claims 20-22,26-27 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 2/22/08.

Claims 19,23-25,28-29 are under consideration.

Claim Rejections - 35 USC § 102

Claims were previously rejected based on the Masor et al. (US 5,602,109) reference. Since the claims have been amended an updated rejection appears below.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 19,28-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Masor et al. (US 5,602,109; first cited with office action dated 4/29/08).

Masor teach enteral formulations containing carbohydrates and other components that alleviate diarrhea (abstract). Masor specifically teach treating diarrhea by administration to human infants in need thereof (claims 16-17). Masor teach the compositions comprising 60 to 110 g/l of carbohydrate and at least 70 mg/l of a nucleotide equivalent one of which is guanosine (claim 17, column 4 lines 25-44), another which is GMP (claim 24, column 4 lines 25-44). Although Masor does not expressly recite the volumes administered, Masor teach typical intakes (ml/day) and feedings (#/day) (Table IX column 17). Further it is noted that there is no limitation in the instant claims as to whether or not the administration occurs in one feeding or multiple feedings. For example, the 831 ml/day as recited in column 17 line 32 corresponds to 50-91 g of carbohydrate and 58 mg guanosine. Thus Masor meet the ranges recited in instant claims 19,28-29. Masor teach that glucose is a specific example of a carbohydrate of the invention (column 5 line 40). Masor teach the composition as a liquid (claim 2 for example) and teach enteral administration (abstract) as recited in the instant claims. It is noted that the claims recite identifying a mammal that suffers from or will suffer from a trauma and state that the composition is administered within 24 hours of the trauma. Since Masor teach the method for treating diarrhea in human infants in need thereof (claims 16-17), a mammal is identified as recited in the instant claims. It is noted that the instant specification provides no specific definition of trauma. In accord with section 2111 of the MPEP the term is given the broadest reasonable interpretation. In the instant case, Masor teach administration to those with diarrhea which is an event that causes distress and disruption and is thus a trauma. Since the trauma is ongoing until the diarrhea ends the administration would be within 24 hours of the occurrence of the trauma. Further, Masor expressly teach that some of the subjects in the studies had diarrhea

(column 18 lines 55-67). It is noted that the claims recite that the method reduces risk of developing multiple organ dysfunction. Such statement is an intended use as it does not result in a structural or manipulative difference. Since Masor teach the active steps of the claims the claim limitations are met.

Response to Arguments 102 Masor

Since the claims have been amended, a new rejection adapted to the claims is recited above using the same reference as in the previous rejection. Applicants arguments will be considered to the extent that they apply to the current rejection and claim set.

Applicants argue that Masor does not teach identifying a mammal or reducing the risk of developing multiple organ dysfunction.

Applicant's arguments filed 7/21/09 have been fully considered but they are not persuasive.

Although Applicants argue that Masor does not teach identifying a mammal or reducing the risk of developing multiple organ dysfunction, Masor teach the method for treating diarrhea in human infants in need thereof (claims 16-17). Thus a mammal is necessarily identified to carry out the method. It is noted that the claims recite that the method reduces risk of developing multiple organ dysfunction. Such statement is an intended use as it does not result in a structural or manipulative difference. Since Masor teach the active steps of the claims the claim limitations are met.

Claim Rejections - 35 USC § 103

This rejection is necessitated by applicants amendments.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 19,23-25,28-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alexander et al. (US 5,231,085; first cited with 4/29/08 office action).

Alexander teach that nutritional therapy by enteral administration is known in the art and that the compromise of the immune system may lead to complications due to multiple organ failure (column 1 lines 19-31). Alexander teach a specific composition (example 1 column 6) which includes a carbohydrate source and guanine. Alexander teach the administration of compositions (examples 2 and 3). Specifically the compositions are taught to be suitable for patients who suffer from post-surgical trauma or trauma (column 5 line 28-36). In example 2 (column 6 line 63-64) the patients have experienced trauma or major general surgery and in

example 3 (column 9 lines 3-4) the patients have undergone major operation. In example 2, the patients are administered composition A (column 7 line 46-47). The amount of composition A was calculated based on energy expenditure (column 7 line 51-55). Alexander teach that the daily amount is usually 1000-2000 kcal/day (column 4 line 10-12). Composition A includes 197.6 g of carbohydrate (in 1500ml so the concentration is 132 g/l) and 0.56-0.77g guanine. Alexander teach enteral administration and liquid compositions (column 9 line 10-11 and column 3 line 56-62 for example).

Composition A as taught by Alexander includes guanine, not guanosine as recited in the instant claims.

Alexander teach a nucleobase or nucleoside (claim 1b, column 2 lines 50-60) as part of the composition. In composition A (column 6) Alexander uses the nucleobase guanine. Alexander teach guanosine as a specific nucleoside (column 2 lines 59-60). Since Alexander teach nucleosides, specifically guanosine, as the nuclobase source one would be motivated to substitute guanine as described in composition A (column 6) with guanosine. Since Alexander teach the administration of composition A (examples 2 and 3) one would be motivated to administer this composition in which guanosine is substituted for guanine. One would have a reasonable expectation of success since Alexander expressly teach that the nucleobase source can be nucleobases or nucleosides (column 2 lines 50-60). In example 2, the patients are administered composition A (column 7 line 46-47). The amount of composition A was calculated based on energy expenditure (column 7 line 51-55). Alexander teach that the daily amount is usually 1000-2000 kcal/day (column 4 line 10-12) thus one would be motivated to use such

amount as an initial amount. Composition A includes 197.6 g of carbohydrate (in 1500ml so the concentration is 132 g/l) and 0.56-0.77g guanine (or guanosine). Further, Alexander recognizes glucose, applicants elected species, as a carbohydrate source (column 7 line 25 for example) thus one would be motivated to use glucose as the carbohydrate source. Thus Alexander motivate the use of guanosine and glucose in the composition at the doses and concentrations as recited in claims 9,28-29.

Alexander specifically teach that the compositions are suitable for patients who suffer from post-surgical trauma or trauma (column 5 line 28-36). In example 2 (column 6 line 63-64) the human patients have experienced trauma or major general surgery and in example 3 (column 9 lines 3-4) the patients have undergone major operation. Thus one would be motivated to identify such patients and administer the composition to patients who have undergone surgery as recited in the instant claims 23-24. Alexander expressly teach that the nutritional supplementation begins within 24 hours of the injury (column 7 lines 21-23) thus meeting the time frame as recited in the instant claims. Further, since example 3 (column 8 lines 66-67) states that the formulation is for patients undergoing major operation one would be motivated to administer the formulation prior to the scheduled operation as recited in instant claim 25 to enhance the immune system as taught by Alexander (claim 1). Alexander teach enteral administration and liquid compositions (column 9 line 10-11 and column 3 line 56-62 for example) as recited in the instant claims.

It is noted that the claims state that the method is for 'reducing the risk of developing organ dysfunction'. Alexander teach that nutritional therapy by enteral administration is known in the art and that the compromise of the immune system may lead to complications due to

multiple organ failure (column 1 lines 19-31). Thus Alexander recognize multiple organ dysfunction as a problem. Further, Alexander obviate the active steps using the claimed components.

The claims would have been obvious because the substitution of one known element (guanosine) for another (guanine) would have yielded predictable results to one of ordinary skill in the art at the time of the invention. In fact, Alexander expressly teach that the nucleobase source can be nucleobases (such as guanine) or nucleosides (such as guanosine) (column 2 lines 50-60). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Prior Art

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

Bistrian et al US 5,320,846. Bistrian teach methods of enterally administering guanosine (claim 1) to patients having trauma or surgery (claim 2). Bistrian teach a carbohydrate source with the formulation (claim 3).

Hageman et al US 6,420,342. Hageman teach nutritional compositions for trauma and surgery (abstract, claim 12). Hageman teach compositions with ribose (abstract, claim 1) and

carbohydrates such as glucose (column 7 lines 10-30). Hageman teach enteral formulations (column 6 line 45).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RONALD T. NIEBAUER whose telephone number is (571)270-3059. The examiner can normally be reached on Monday-Thursday, 7:30am-5:00pm, alt. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Anish Gupta/
Primary Examiner, Art Unit 1654

/Ronald T Niebauer/
Examiner, Art Unit 1654